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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,544	11/14/2003	R. Steven Davidson	57778.8001.US01	7965

34055 7590 05/12/2009
PERKINS COIE LLP
POST OFFICE BOX 1208
SEATTLE, WA 98111-1208

EXAMINER	
EBRAHIM, NABILA G	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
05/12/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/713,544	DAVIDSON, R. STEVEN	
	Examiner	Art Unit	
	Nabila G. Ebrahim	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/24/2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *1-12, 19-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-18,25 and 26* is/are rejected.

7)☒ Claim(s) *13-18,25 and 26* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/24/2008 has been entered.

The receipts of claim amendments and Applicant's remarks dated 12/24/2008 is acknowledged.

Status of Claims:

Claims 1-26 are pending in the application.

Claims 13-18 and 25-26 are under current examination.

Claims 1-12 and 19-24 were withdrawn from consideration due to restriction requirements.

Priority

Applicant claims priority to provisional applications 60/426598 and 60/497186. Solely, the latter application teaches the powder matrix recited in the instant claims. Thus, the priority date of this limitation will be dated as 08/22/2003.

Previous rejections that are not reiterated in the current office actions are withdrawn.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 13 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/20861 (hereinafter Brown).

Brown discloses solid dosage form that can be in the form of a sheet or film (page 1, lines 11 and 19); the dosage form is coated with a dry powder coating (page 5, lines 27 and 28; claim 3). The film may be designated to treat cough (page 29, line 30), (chlorphneramine maleate is intended to treat cough and is included in the famous antitussives such as Robitussin®). The film and the coating both contain biologically active pharmaceutical material (pages 4 and 5).

3. Claims 13-16, and 25-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Acharya et al. WO 0059423 (hereinafter Acharya).

Acharya discloses a multi layer composition in the form of a film or tablet, where a basal layer that includes a non-plasticized PVP mucoadhesive composition that may or may not contain active agent (page 14, lines 6-9). The mucoadhesive layer is prepared as a dry mix (page 14, line 28 to page 15, line 3) meeting the powder coating matrix of the claims. The system is intended to treat cough (page 13, lines 10+). The film may include menthol, benzocaine, nutritional supplements such as vitamins, herb extracts or minerals, and mixtures thereof (page 7, lines 25+ and page 13, lines 17+). In addition, it includes odorants for masking or refreshing objectionable breath such as mint, spearmint, menthol, or cherry (page 13, lines 13+). Note that pharyngitis is always accompanied by bad breath and objectionable odor. Gelatin, pectin, and starches are comprised in the film (page 2, lines 22+). Further, Acharya teaches the use of acesulfame potassium (see examples). The presence of benzocaine in the formula reads on the limitation of claims 26 since the drug is known to cause numbness.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 13-18 and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Brown WO 98/20861 or Acharya et al. WO 0059423 in view of Leung et al. US 7025983 (Leung).

Brown teaches films coated with powder matrix to treat cough. The reference is deficient in teaching the ingredients recited in the claims. The reference was discussed supra.

Acharya teaches films to treat cough and pharyngitis which is coated by powder matrix and comprises herbs extracts, vitamins, minerals, water, cherry flavor, menthol, acesulfame potassium, pectin, and benzocaine. The reference is relied upon for the reasons set forth supra.

The two references are deficient in teaching carrageen, sucralose, lecithin, glycerin, preservatives, polysorbate, and carboxymethyl cellulose recited in instant claims 17 and 18.

Leung teaches fast dissolving orally consumable films which are used to deliver breath deodorizing agents, antimicrobial agents and salivary stimulants to the oral cavity. The films can also be used to deliver pharmaceutically active agents [0001] such as antitussives, expectorants, decongestants, antihistamines, [0102-0106], note that all these drugs are known to treat pharyngitis and cough. It is also noted that the mouth bad odor is a symptom associated with pharyngitis. Consequently it would improve a condition of pharyngitis. The film also comprises menthol (abstract) and a film-forming material such as pectin [0033] in an amount from about 0.01 to about 99 wt %, preferably about 30 to about 80 wt %. Since other ingredients are recited in instant claim 17 in an amount that is possible to be 0%, then these ingredients are not limiting the claims. Pectin is used in amounts ranging from about 45 to about 70 wt % of the film and even more preferably from about 60 to about 65 wt % of the film [0033]. Further, Leung teaches menthol which can be added from about 0.01 to about 15 wt % of the composition, preferably about 2.0 to about 10 wt % and even more preferably from about 3 to about 9 wt % of the film [0031]. The film may contain water [0034] in an amount of about 0.1 to about 8 wt %

(claim 10), an amount of about 0.1 to about 15wt % of at least one flavoring agent (claim 10) which may be cherry [0052]. Leung also teaches acesulfame-K (a sweetening agent), the free acid form of saccharin [0047] in an amount of about 0.1 to about 15 wt % (claim 10). Carrageenan is taught in amounts ranging from about 0 to about 10 wt %, preferably about 0.1 to about 2 wt % of the film [0042]. Sucralose is also disclosed as a sweetener agent. Leung teaches the use of lecithin, in amounts ranging from about 0.01 to about 0.7 wt % of the film [0042]. Examples 2-4 use glycerin [0148] in an amount of 2% (table 2). Leung teaches that a preservative may be added in amounts from about 0.01 wt % to about 1 wt % of the film and that the preferred preservatives include sodium benzoate [0121]. Polysorbate 80 is also used in an amount between 0.355 to 0.4 % (table 2) and a preferred thickening agents include carboxyl methylcellulose, and the like, in amounts ranging from about 0.01 to about 5 wt % [0043].

Regarding the limitation in claims 17 and 18 which recites that the pectin may be replaced with one or more of the groups consisting of gelatin, maltodexrin, modified food starch, TiO2, and acacia gum, it is noted that Leung recognized that some of these film-formers such as gelatin, high amylose starch and acacia gum are usable as film-formers in the invention, accordingly, it would have been obvious to a person of ordinary skill in the art to replace one of these substances with the other or replace some of the amount used by another substance to advance a specific property in the film produced such as rigidity, thickness or thinning, etc.

Note that the references, disclose the combination of water, cherry flavor, carrageenan, acesulfame potassium, sucralose, lecithin, benzocaine, glycerin, sodium benzoate, polysorbate, menthol, carboxymethyl cellulose, pectin and vitamin E in amounts that overlap or differ in a small amount. It has been held that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See In re Aller, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955). Furthermore,

the claims differ from the reference by reciting various concentrations of the active ingredients. However, the preparation of various pharmaceutical compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. See In re Russell, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

Thus, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to combine the ingredients in the amounts or after adjusting the amounts taught by Leung to the powder matrix coated film disclosed by Brown or Acharya to treat pharyngitis and/or cough since the three references teach a film or thin sheet having pharmaceuticals that improves cough and pharyngitis. The person of ordinary skill would be motivated by the fact that film formed dosage forms are easier in administration and can work locally and systemically on a patient in need of the drug and the artisan would have reasonable expectation of success of achieving the needed effect of such drugs.

Response to Arguments

Applicant's arguments with respect to claims 13-18 and 25-26 have been considered but are moot in view of the new ground(s) of rejection including Brown and Acharya.

Applicant argues Leung as the primary reference and as lacking the powder matrix and failing to treat cough or pharyngitis as required by amended claim 1. However, Leung teaches anti-tussives in the disclosure and most of the drugs disclosed can improve pharyngitis such as anti-histamines and mouth lubricants. In addition, the powder matrix is disclosed by newly introduced references Brown and Acharya.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nabila G. Ebrahim whose telephone number is 571-272-8151. The examiner can normally be reached on 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nabila G Ebrahim/
Examiner, Art Unit 1618

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618